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Sede Legale e Amministrazione
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QUALITY CONTROL CERTIFICATE

KIT NAME ENZYWELL HERPES SIMPLEX 2 IgM

Code 91025

LOT.NO

234-A



2024-04



2023-01

REAGENTS

CODE	LABEL	DESCRIPTION	LOT	EXP	NO
PF93000	007250	MICROPLATE	666	2024-04	1
PF93900/HSV	C4960	NEGATIVE CONTROL	782	2024-07	1
PF92355	007280	POSITIVE CONTROL	203	2024-07	1
PF30056	011560	CONJUGATE	222	2024-04	1
PF91722	007300	ANTIGEN	226	2025-09	6
PF93611	009660	DILUENT 2	228	2024-07	1
PF93603	1035	WASHING BUFFER 10x	457	2024-08	1
PF93602	1032/RISK0	STOP SOLUTION	215-5	2024-08	1
PF93619	1034	SUBSTRATE-HS	372	2024-07	1
PF30057	011570	CUT OFF CONTROL	215	2024-07	1

CONTROLS

	FOUND RESULTS	EXPECTED RESULTS
NEGATIVE CONTROL	0.085	< 0,6 Cut Off
CUT OFF CONTROL	0.342	≥ 0.200
POSITIVE CONTROL	2.221	> 1,5 Cut Off
CV %	13%	≤ 15%

*Evaluation of the method according to the package inset in the attached document
This batch has been manufactured and checked according to quality requirements.
Hereby, it is released to distribution.*

APPROVED BY: RESPONSIBLE HEAD, Quality Control Reagents

DATE:

05.05.2023

WARNING: POTENTIAL BIOHAZARDOUS MATERIAL!

This kit may contain some reagents made with human serum or plasma. All serum or plasma used has been tested by an and found non-reactive for HIV-1/2, HCV and HBsAg. Because no method can offer complete assurance that HIV-1/2, HCV, HBsAg or other infectious agents are absent, reagents should be handled with maximum attention.

IO 09- 005-V



CODE 91025
CODE 91187

QUALITY CONTROL CERTIFICATE

Annex: Method Evaluation

NAME KIT	HERPES SIMPLEX 2 IgM
LOT.	234
DATE OF TEST	24/02/2023

METHOD: ACCORDING TO THE PACKAGE INSERT

	FOUND		EXPECTED
1. SOLID PHASE			
A) UNIFORMITY BETWEEN PLATES			
1st PLATE	OD 450 nm	1.799	
	CV%	4%	< 20%
2nd PLATE	OD 450 nm	1.772	
	CV%	6%	< 20%
B) UNIFORMITY WITHIN PLATE			
	OD 450 nm	1.792	
	CV%	7%	< 15%
2. BULK CONTROL date: 15/02/2023			
A) Average OD of Cut Off Control	OD 450 nm	0.455	≥ 0.200
B) Index of Negative and Positive Sera		accepted	According to specification
C) Sensitivity with working calibrators		accepted	According to specification
3. FINAL CONTROL date: 24/02/2023			
A) Blank	OD 450 nm	0.045	≤ 0.100
B) Average OD of Negative Control	OD 450 nm	0.085	< 0,6 Cut Off
C) Average OD of Cut Off Control	OD 450 nm	0.342	≥ 0.200
D) Average OD of Positive Control	OD 450 nm	2.221	> 1,5 Cut Off
E) HOMOGENEITY OF CUT OFF	No.	6	
	OD 450 nm	0.387	
	CV%	13%	≤ 15%
F) PRECISION OF FILLING PROCESS			

☒ SATISFACTORY

☐ UNSATISFACTORY

FINAL RESULT: ACCEPTED

Date: 24.02.2023

Signed:

Released: Q.C.Manager